



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,994	12/15/2003	Edward L. Paul JR.	2C03.1-332	6442
23506	7590	03/14/2006	EXAMINER	
GARDNER GROFF SANTOS & GREENWALD, P.C. 2018 POWERS FERRY ROAD SUITE 800 ATLANTA, GA 30339			GEDEON, BRIAN T	
		ART UNIT	PAPER NUMBER	
		3766		

DATE MAILED: 03/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/736,994	PAUL, EDWARD L.
	Examiner	Art Unit
	Brian T. Gedeon	3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 15 December 2003.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-52 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) 40 is/are allowed.
 6) Claim(s) 1-38 and 41-52 is/are rejected.
 7) Claim(s) 39 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 2/15/2005 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date: _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>4/21/05, 10/1/04, 6/14/04</u>	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Claim Objections

1. Claim 40 is objected to because of the following informalities: the first and second electrodes are redundantly claimed. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 2, 7, 13, 19, 29, 42, and 48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The disclosure and claims fail to provide enough information to enable one skilled in the art to comply with the FDA requirements of safety and efficacy regarding the claimed invention. Specifically, no guidelines are set forth for fulfilling this requirement.
3. Claims 2, 7, 13, 19, 29, 42, and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 1, 34, and 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The disclosure is indefinite as to how the claimed apparatus produces results better than placebo, or achieves improvement in a specific percentage of a population of study subjects.

5. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: structure pertaining to generate the microcurrent signal, applying the signal to the ocular tissue, nor the period of time, frequency, and amplitude of applied signal.

6. Claims 2-4, 8, 9, 14, 15, 22, 23, 30, and 31 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the rejected claims recite mere results achieved by implementation of the apparatus and fail to limit the structure of the independent apparatus claims from which they depend.

7. Claims 43, 44, 49, and 50 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the rejected claims

recite mere results of achieved by the claimed method of therapy and fail to further limit the method by claiming steps as to how the results are achieved.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 5, 41, and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Wallace et al. (US Patent no. 5,522,864).

In regards to claims 1 and 41, Wallace et al. discloses an apparatus and method for ocular treatment in which an electrode 22 is in contact with a closed lid of a patient's eye. The electrode 22 is coupled to an electric current generator 25 which is designed to deliver a constant current of between 5 microamps and 1 milliamp, preferably 200 microamps, to the eye for treatment of ocular diseases, col 2 lines 49-67. The constant current of 200 microamps was applied for 10 minutes in a cited example of case history, col 5 lines 15-17. Further, seven examples of patient case history recited by Wallace et al. show that transocular electrical stimulation led to improvements in the patients' visual fields, therefore it would seem inherent that this therapy produces better results than a placebo.

In regards to claims 5 and 45, the ocular disease of interest to Wallace et al. is macular degeneration, col 1 lines 42-45 and col 4 lines 20-23.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 18, 28, 36, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rossen (US Patent no. 4,989,605).

In regards to claims 18, 28, and 36, Rossen discloses an apparatus with an electrical circuit means for generating a current in the range of 25 to 900 microamps in the form of a DC carrier signal which is modulated on and off, col 2 lines 11-21. The said DC carrier signal is modulated by a frequency selected from two pairs of frequencies, which exhibit specific therapeutic action, col 1 lines 66-68. A modulation oscillator 46 and carrier oscillator 48 are connected to the said electrical circuit to carry out DC carrier signal modulation, col 4 lines 40-45. The said modulation frequencies exhibit therapeutic action; specifically two modulating frequencies are used. The first modulating frequency is lower than the second modulating frequency, but exhibits a longer time period than the said second frequency, col 5 lines 46-52 and Figure 4. The application of said second frequency after application of said first frequency is found to be useful, col 2 lines 30-32. Rossen et al. does not teach the use of controller logic or application of the higher frequency before the lower frequency. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to

implement a programmable microcontroller or microprocessor in communication with the electrical signal generating circuits because it has become increasingly common in the electrical therapy art in order to better adjust therapy and control various functions of a device at once. It would also have been obvious to apply a first modulation frequency having high frequency and short time period sequentially followed by a second frequency having a lower frequency value with longer time period since it merely involves a reversal of the frequency application disclosed by Rossen, and it has been held that mere reversal of parts involves only routine skill in the art. *In re Einstein*, 8 USPQ 167.

Further in regards to claim 28, Rossen substantially describes the claimed invention, except for the application of a third modulation frequency. It would have been obvious to apply a third frequency in view of the rejection made towards claims 23 and 41 above, and the addition of a third frequency is considered to be a mere duplication of an essential working part or step that involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

10. Claims 6, 10, 12, 26, 19, 20, 24, 32, 34, 35, 37, 38, 47, and 51, are rejected under 35 U.S.C. 103(a) as being unpatentable over Rossen (US Patent no. 4,989,605) in view of Wallace et al. (US Patent no. 5,522,864).

In regards to claims 6 and 34, Rossen discloses electrical circuit means for supplying to a pair of electrodes with current in the range of 25 microamps to 900 microamps in the form of a DC carrier signal modulated on and off in time at a different

frequency, col 2 lines 11-21. However, Rossen et al. does not disclose applying this apparatus to treat ocular tissue of a patient. Wallace et al. has an electrode 22 connected to a current generator 25, col 2 lines 51-53. The current generator 25 of Jarding et al. is capable of applying a DC current of 5 microamps to 1 milliamp, but preferably 200 microamps, in order to treat ocular disease, col 2 lines 64-64. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the microcurrent stimulation circuit of Rossen et al. with the teachings of Wallace et al. regarding microcurrent stimulation since it is known in the art that microcurrent therapy is effective in treating various visual diseases.

In regards to claims 10, 16, 24, 32, and 51, Rossen describes the apparatus of the claimed invention except for the application of treating visual diseases. Wallace et al. teaches the application of microcurrent therapy to treat ocular disease, in particular Wallace et al. is directed to treating macular degeneration, col 2 lines 64-66. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made combine the elements and teachings of the above references to treat macular degeneration since Wallace et al. teaches it.

In regards to claims 12 and 35, Rossen describes the claimed invention except for the application of microcurrent stimulation to treat ocular disease. Wallace et al. describes an apparatus and method of applying a microcurrent (i.e., 200 microamps) to treat macular degeneration. The apparatus described by Wallace et al. describes an electrode 22 connected to the positive output terminal of a current generator 25, col 2 lines 49-54. The electrode is configured to be placed in electrical contact with a closed

Art Unit: 3766

eyelid of a subject 20, col 2 lines 4-11. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to place an electrode on a closed eyelid since Wallace et al teaches it.

In regards to claims 19 and 37, Rossen describes the claimed invention except for first electrode connected to the electrical circuit via the positive terminal to apply microcurrent to the ocular tissue nor the second electrode connected electrical circuit via the negative terminal placed in contact with a location on the user's body. Wallace et al. describes an apparatus and method for ocular treatment via application of a microcurrent (i.e., 200 microamps) from an electrode 22 placed on the subject's 20 closed eyelid and an electrode 24 attached to another body location, e.g. the occipital location of the subject's 20 head, col 2 lines 49-67. The electrode 22 placed in contact with the subject's 20 closed eyelid is connected to the positive terminal of the electrical circuit and the occipital electrode 24 is connected to the negative terminal, col 2 lines 51-56. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use one positive electrode and one negative electrode connected to different locations of a subject's body in order to generate a complete loop in order for current to flow.

In regards to claims 20 and 38, Rossen describes the claimed invention except for an electrode connected to the positive terminal being coupled to a pad for contact with the closed eyelid of a subject. Wallace et al. uses a sponge electrode 22 connected to the positive terminal of the electrical circuit, and is placed in contact with the closed eyelid of the subject 20, col 2 49-54. The electrode 22 delivers microcurrent

therapy for ocular diseases, col 2 lines 64-66. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to put an electrode in contact with a patient's eye to deliver therapy for an ocular disorder since Wallace et al. teaches it.

11. Claims 11, 17, 25-27, 33, 46, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rossen (US Patent no. 4,989,605) in view of Wallace et al. (US Patent no. 5,522,864) further in view of Jarding et al. (US Patent no. 6,035,236).

In regards to claims 11, 17, 25, 33, 46, and 52, Rossen in view of Wallace et al. substantially describe the invention as claimed except for treating at least one of the ocular disorders listed in the claim. Jarding et al. teaches a method and apparatus for treating ocular disorder such as macular degeneration and retinitis pigmentosa, col 2 lines 39-41. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply microcurrent therapy to ocular disorders other than macular degeneration since Jarding et al. teaches it.

In regards to claim 26, Rossen discloses electrical circuit means for supplying to a pair of electrodes with current in the range of 25 microamps to 900 microamps in the form of a DC carrier signal modulated on and off in time at a different frequency, col 2 lines 11-21. However, Rossen does not disclose applying this apparatus to treat ocular tissue of a patient. Wallace et al. has an electrode 22 connected to a current generator 25, col 2 lines 51-53. The current generator 25 of Jarding et al. is capable of applying a DC current of 5 microamps to 1 milliamp, but preferably 200 microamps, in order to treat

Art Unit: 3766

ocular disease, col 2 lines 64-64. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the microcurrent stimulation circuit of Rossen et al. with the teachings of Wallace et al. regarding microcurrent stimulation since it is known in the art that microcurrent therapy is effective in treating various visual diseases. Rossen in view of Wallace et al. only mention treatment of macular degeneration. Jarding et al. teaches a method and apparatus for treating ocular disorder such as macular degeneration and retinitis pigmentosa, col 2 lines 39-41. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply microcurrent therapy to ocular disorders other than macular degeneration since Jarding et al. teaches it.

In regards to claim 27, Rossen describes the claimed invention except for the application of microcurrent stimulation to treat ocular disease. Wallace et al. describes an apparatus and method of applying a microcurrent (i.e., 200 microamps) to treat macular degeneration. The apparatus described by Wallace et al. describes an electrode 22 connected to the positive output terminal of a current generator 25, col 2 lines 49-54. The electrode is configured to be placed in electrical contact with a closed eyelid of a subject 20, col 2 lines 4-11. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to place an electrode on a closed eyelid since Wallace et al. teaches it.

Allowable Subject Matter

12. Claim 40 is allowed.

13. Claim 39 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The allowed and object to claims recite structure by microcurrent stimulation therapy for an ocular disorder in which therapy is administered through electrodes placed in goggles. The prior fails to describe the invention with the claimed features, therefore the Examiner deems claim 40 as allowable over the prior art and considers claim 39 to contain allowable subject matter.

Double Patenting

14. Claims 1-52 of this application conflict with claims 1-5, 11-50, and 56-62 of Application No. 10/738,921. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Art Unit: 3766

15. Claims 1-52 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-5, 11-50, and 56-62 of copending Application No. 10/738,921. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Chen et al. (US 2005/0209656) discloses a method for applying microcurrent to the eyes.

The Ohno reference and the Sinitzyn et al. reference cited by the applicant were not considered in prosecution of this case because appropriate English translations of the references were not supplied.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272 3447. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272 6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brian T. Gedeon
Patent Examiner
Art Unit 3766



Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766

BTG